Remarks

Claims 1-2, 4, 8, and 13-22 are pending in this application. Claims 3, 5-7, 9-12 and 23-25 have been previously canceled without prejudice or disclaimer. Claims 1 and 2 have been amended for the sole purpose of advancing prosecution.

Claim 1 has been amended to recite "A compliance monitor for a drug delivery device with a mouthpiece for administering a drug, comprising: a switch actuatable by a user on delivering a dose from a drug delivery device; a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose; and a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated; wherein the compliance monitor is removably attachable to the mouthpiece of the drug delivery device; and wherein the sensor is a temperature sensor for sensing body temperature and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth." Support for this amendment appears throughout the specification and claims as originally filed, for example, at FIG. 2 and the last two paragraphs of page 2 of the present specification.

Claim 2 has been amended to recite "The compliance monitor according to claim 1, wherein the compliance monitor comprises a housing and the sensor is mounted at the end of a protruding portion of the housing such that the sensor does not affect the normal operation of the drug delivery device." Support for this amendment appears throughout the specification and claims as originally filed, for example, the sixth full paragraph on page 5 of the present specification.

Applicants, by cancelling or amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the claims cancelled herein or the original claim scope of any claim amended herein, in a continuing application.

No new matter has been added.

In view of the remarks set forth herein, further and favorable consideration is respectfully requested.

I. At page 2 of the Official Action, claim 2 is rejected under 35 USC § 112, 2nd paragraph, as being indefinite.

The Examiner asserts that the phrase "the sensor is positioned externally to the drug delivery device mouthpiece" is indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Further, the Examiner refers to the previous Office Action where the Examiner asserts it is unclear how one is to infringe claim 2 without the drug delivery device present, and also inquires "What structural limitation of the monitor does this claim further limit?"

In view of the following, this rejection is respectfully traversed.

Applicants respectfully submit that claim 2, as submitted in the Response filed May 19, 2011, met the requirements of 35 USC §112, second paragraph. The claim stated that the sensor is positioned externally to the drug delivery device mouthpiece. Therefore, the position of the sensor was clearly recited in claim 2. However, solely to advance prosecution and further clarify the claimed subject matter, Applicants have amended claim 2 to recite that "the compliance monitor comprises a housing and the sensor is mounted at

the end of a protruding portion of the housing such that the sensor does not affect the normal operation of the drug delivery device."

As can be seen, amended claim 2 clearly recites the position of the sensor on the compliance monitor to be the end of the protruding portion of the housing. The amendments to claim 2 provide the clarity necessary for one to understand how to infringe this claim, and also provide further structural limitations to claim 1. Therefore, Applicants respectfully submit that claim 2 meets the requirements of 35 USC § 112, second paragraph.

Accordingly, Applicants submit that the claims are clear and definite. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

II. At pages 2-4 of the Official Action, claims 1, 2, 4, 8, and 13-22 have been rejected under 35 USC § 103(a) as being unpatentable over Burns et al. (US 5,284,133) in view of Sprinkel, Jr. (US 5,261,424).

The Examiner maintains that Burns et al. teach a compliance monitor for a drug delivery device with a mouthpiece comprising a switch, a lip sensor arrangement including a pair of spaced apart electrical contact at the mouthpiece which is connected to the controller by wire. Further, the Examiner asserts Burns et al. teach that when the patient presses the contacts together with his mouth during actuation, delivery of the drug to the patient is confirmed. The Examiner acknowledges that Burns et al. do not teach that the sensor is a temperature sensor. The Examiner alleges Sprinkel teaches a flavor generator with a piezoelectric sensor that can be used to detect the change in temperature that occurs when the flavor generator is placed in between the user's lips. The Examiner concludes that it would have been obvious to one of ordinary skill in the

art at the time of the invention to modify the device of Burns et al. by using a temperature sensor as taught by Sprinkel as an obvious equivalent means for detecting lips being placed upon a mouthpiece. Further, the Examiner states that since the specification recites that the sensor can be a light sensor, conductivity sensor or temperature sensor, there is no criticality in the type of sensor used.

In view of the following, this rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *See KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 at 417-418. Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18

USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Applicants submit that a *prima facie* case of obviousness has not been established because whether taken alone, or in combination, neither Burns et al. nor Sprinkel teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson*.

Claim 1 is directed to a compliance monitor for a drug delivery device with a mouthpiece for administering a drug, comprising: a switch actuatable by a user on delivering a dose from a drug delivery device; a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose; and a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated; wherein the compliance monitor is ***removably attachable to the mouthpiece*** of the drug delivery device; and wherein the sensor is a temperature sensor for sensing body temperature and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth.

Solely in an effort to advance prosecution, Applicants have amended claim 1 to recite that the compliance monitor is ***removably attachable to the mouthpiece*** of the drug delivery device. In contrast, Burns et al. only teach that the three components - the timer (26), actuating means (28) and the signaling device (30) - can be ***separate from the controller*** (24). Further, Burns et al. merely teach that the mouthpiece can be removed from the ***drug-containing canister*** (10). Nowhere does Burns et al. teach or

suggest that ***any*** of these recited components can be ***removably attachable to the mouthpiece*** of the drug delivery device. Therefore, Burns et al. do not teach or suggest that the monitoring device is ***removably attachable to the mouthpiece*** of the drug delivery device, as presently claimed.

Sprinkel does not remedy the deficiencies of Burns et al. Sprinkel describes electrically heated flavor generators without any removably attachable parts. The Examiner acknowledges that Sprinkel does not teach a compliance monitor that is removable. The Examiner notes that Sprinkel is only used to teach an equivalent type of sensor for detecting whether the device is properly used. Accordingly, Sprinkel does not describe a compliance monitor that is removably attachable to any portion of the drug delivery device, much less the mouthpiece of the drug delivery device as presently claimed.

Applicants submit that the combination of references do not describe using a compliance monitor for a drug delivery device with a mouthpiece for administering a drug, comprising: a switch actuatable by a user on delivering a dose from a drug delivery device; a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose; and a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated; wherein the compliance monitor is ***removably attachable to the mouthpiece*** of the drug delivery device; and wherein the sensor is a temperature sensor for sensing body temperature and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth.

Accordingly, whether taken alone, or in combination, none of the cited references teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson*.

In view of the foregoing, it is submitted that, whether taken alone or in combination, Burns et al. and Sprinkel do not render the presently pending claims obvious within the meaning of 35 USC § 103(a). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

CONCLUSION

Applicants assert that the claims are in condition for immediate allowance and early notice to that effect is earnestly solicited. Should the Examiner deem that any further action by Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP

/Sheldon M. McGee/
Joshua B. Goldberg
Registration No. 44,126
Sheldon M. McGee
Registration No. 50,454
Robert M. Joynes
Registration No. 54,842
Customer No. 34375

Date: October 10, 2011
THE NATH LAW GROUP
112 South West Street
Alexandria, Virginia 22314
Tel: (703) 548-6284
Fax: (703) 683-8396